#16

Express Mail No.
EI187449230US

BOS/3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Peter Rice et al.
Application No.	:	09/699,224
Filed	:	October 27, 2000
Confirmation No.	:	8386
For	:	PEPTIDE MIMICS OF CONSERVED GONOCOCCAL EPITOPES AND METHODS AND COMPOSITIONS USING THEM
Group Art Unit	:	1645
Examiner	:	S. Devi

New York, New York
August 26, 2003

Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION OF PETER A. RICE, JUTAMAS NGAMPASUTADOL AND SUNITA GULATI UNDER 37 C.F.R. § 1.131

We, PETER A. RICE, a citizen of the United States, residing at 55 Norfolk Road, Chestnut Hill, Massachusetts 02467, USA, JUTAMAS NGAMPASUTADOL, a citizen of Thailand, residing at 8 St. Paul Street, Cambridge, Massachusetts 02139, USA, and SUNITA GULATI, a citizen of the United States, residing at 14 Wheeler Street, Gloucester, Massachusetts 01930, USA, hereby declare and state as follows:

1. We are the co-inventors of the claimed subject matter in the above-identified patent application.

2. We have been informed by our attorneys that the Examiner has rejected, *inter alia*, the following claims in the February 26, 2003 Office Action in this application:

claims 1-3, 10-13 and 15, as anticipated by the disclosure of Ngampasutadol *et al.*, Abstracts of the Eleventh International Pathogenic Neisseria Conference, Nassif *et al.*, Eds., p. 159 (1998) ("Ngampasutadol *et al.*"); and claims 1-15 as obvious over the disclosure of Ngampasutadol *et al.*

3. We make this Declaration to establish that we conceived and reduced to practice the inventions of claims 1-15 in the United States before November 1, 1998, the publication date of the Ngampasutadol *et al.* abstract.

4. At the time we conceived and reduced to practice these inventions, we were all employed by Boston Medical Center.

5. Prior to November 1, 1998, we conceived and reduced to practice the following:

Claim 1. A peptide mimic of a conserved gonococcal epitope not found on human blood group antigens, wherein said peptide mimic is capable of inducing in a mammal an immune response against said conserved gonococcal epitope.

Claim 2. The peptide mimic according to claim 1, wherein the amino acid sequence of the peptide mimic comprises the sequence DE_GLF.

Claim 3. The peptide mimic according to claim 1, wherein the immune response is T-cell dependent.

Claim 4. The peptide mimic according to claim 1 or 2, wherein the amino acid sequence of the peptide mimic comprises cysteine residues at each terminus.

Claim 5. The peptide mimic according to claim 4, wherein a cyclic peptide is formed through disulfide bridges between the cysteine residues at each terminus of said sequence.

Claim 6. The peptide mimic according to claim 5, wherein the peptide mimic further comprises at least one tail for coupling to a second agent.

Claim 7. The peptide mimic according to claim 6, wherein the second agent is an adjuvant.

Claim 8. The peptide mimic according to claim 1 or 2, wherein the peptide mimic further comprises an adjuvant or a carrier protein.

Claim 9. The peptide mimic according to claim 1 or 2, wherein the peptide mimic is part of a multiple antigen peptide.

Claim 10. The peptide mimic according to claim 1 or 2, wherein said peptide mimic competes with gonococcal LOS for binding to monoclonal antibody 2C7.

Claim 11. A peptide mimic which immunospecifically binds to an antibody that binds to an oligosaccharide epitope of *N. gonorrhoeae*, which oligosaccharide epitope is not present in human blood group antigens.

Claim 12. The peptide mimic according to claim 11, wherein the peptide mimic binds to monoclonal antibody 2C7.

Claim 13. The peptide mimic according to claim 11, wherein the peptide mimic binds to a monoclonal antibody produced by immunizing a mammal with an anti-idiotypic monoclonal antibody, or fragment thereof, produced by a hybridoma cell line having the characteristics of HB 11311 as deposited with the ATCC.

Claim 14. The peptide mimic according to claim 11, wherein the peptide mimic is part of a multiple antigen peptide.

Claim 15. A composition for immunizing against *N. gonorrhoeae* infection comprising an immunoprophylactically effective amount of a peptide mimic according to any one of claims 1-3, 5-7, 9 or 11-14.

6. We have attached hereto, as Exhibit A, a true copy of a page from one of Dr. Ngampasutadol's research notebooks. The data shown on this page were generated in experiments conceived and conducted by us prior to November 1, 1998 and the entries on this page were made by Dr. Ngampasutadol prior to November 1, 1998 according to her regular and routine practice of keeping laboratory notebooks. The data show the peptide sequences of PEP1-7, which are recited throughout the specification and in Figure 1 of the present application. These data were and are considered to be confidential.

7. We have attached hereto, as Exhibit B, a true copy of another page from one of Dr. Ngampasutadol's research notebooks. The data shown on this page were generated in experiments conceived and conducted by us prior to November 1, 1998 and the entries on this page were made by Dr. Ngampasutadol prior to November 1, 1998 according to her regular and routine practice of keeping laboratory notebooks. The data show the inhibition of mAb 2C7 binding to LOS by the peptide sequences, PEP1-7, which are recited throughout the specification and Figure 1 of present application. The inhibition of mAb 2C7 binding to LOS by PEP1-7 demonstrates that PEP1-7 binds competitively to LOS. These data were and are considered to be confidential.

8. Exhibits A and B establish that we had completed our claimed inventions related to peptide mimics of conserved gonococcal epitopes prior to the publication of the Ngampasutadol *et al.* abstract relied upon by the Examiner.

9. We declare further that all statements made herein of our own knowledge are true and that all statements made herein on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, United States Code, and that such willful false statements may jeopardize the validity of this application and any patent issuing thereon.

Peter A. Rice

Peter A. Rice

Signed at

this 19th day of August, 2003.

Jutamas Ngampasutadol

Jutamas Ngampasutadol

Signed at

this 19th day of August, 2003.

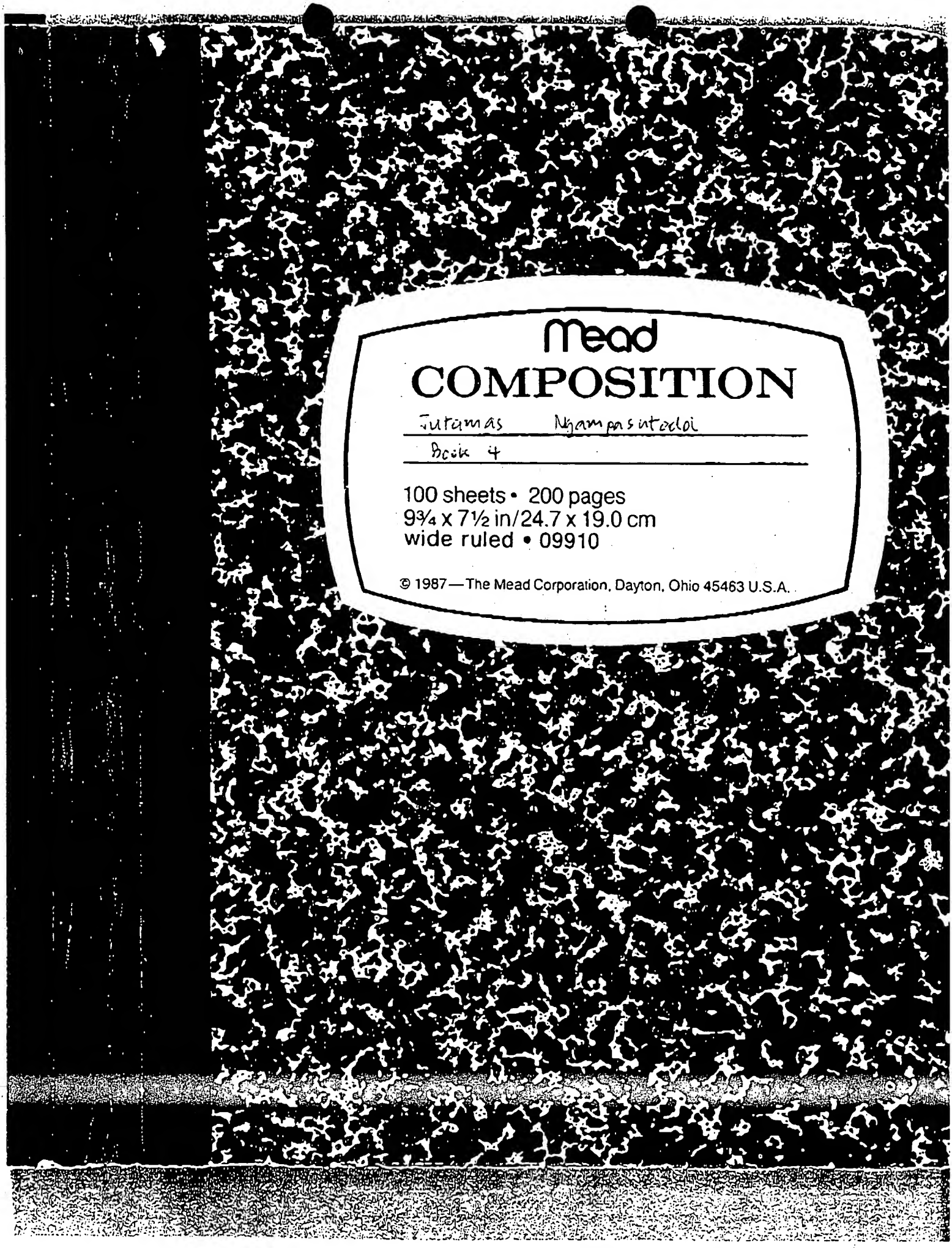
Sunita Gulati

Sunita Gulati

Signed at

this 19th day of August, 2003.

EXHIBIT A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COMPOSITION
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Book 4
100 sheets • 200 pages
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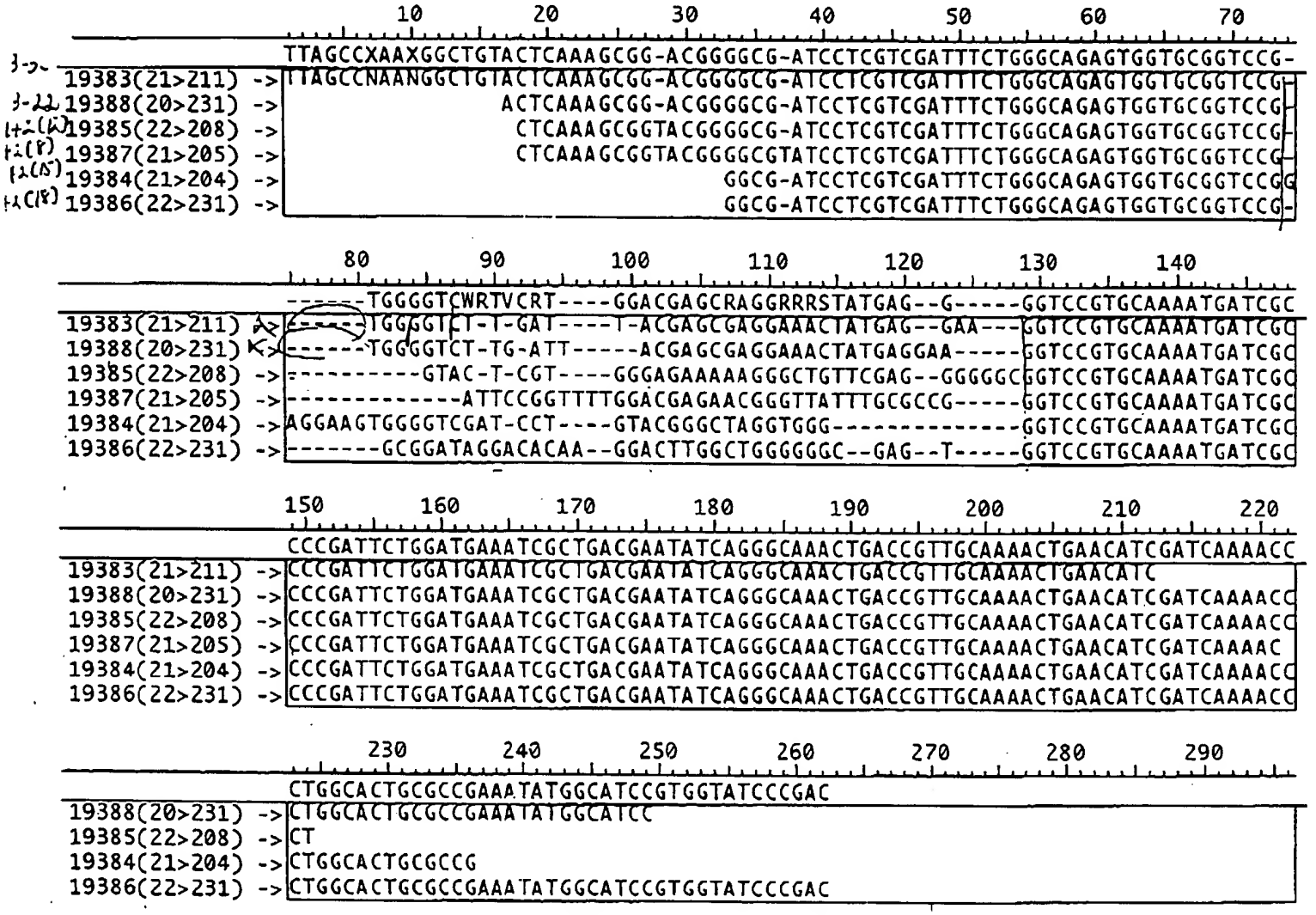


3-27, 3-27 3-30,

3-22 WGLDYERGNYEE → PEP 2 (C)

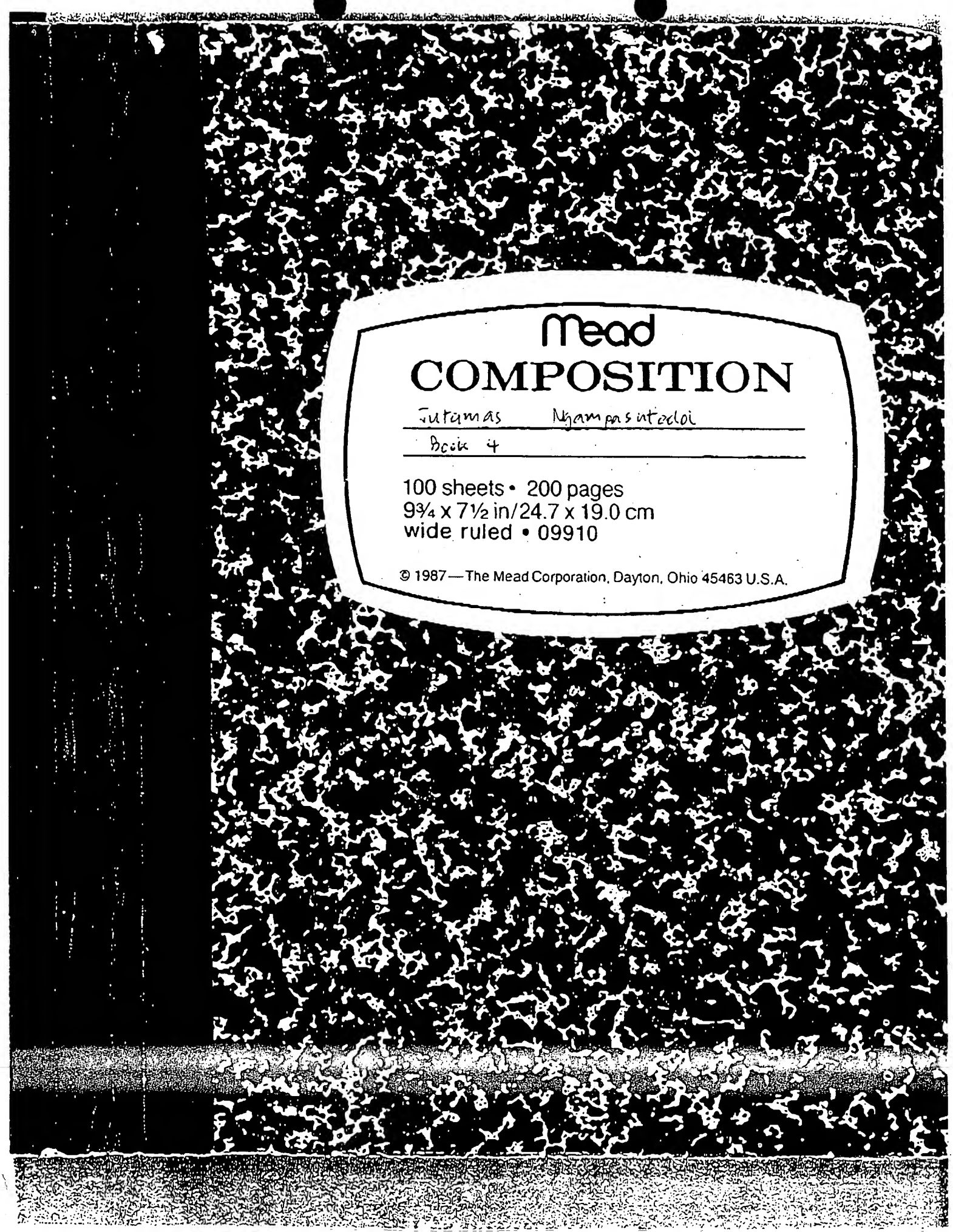
1+2(12) VLVGEKGLFEGG - PEP 4(

1+2(F) IIVLDENGLPAP → PEP 1 (3)

1+2(15) EEVGSILYGLGG - PEP 7

1+2(18) ADRTQGLGWGAE~~ES~~ S PEP 6

EXHIBIT B


Mead
COMPOSITION
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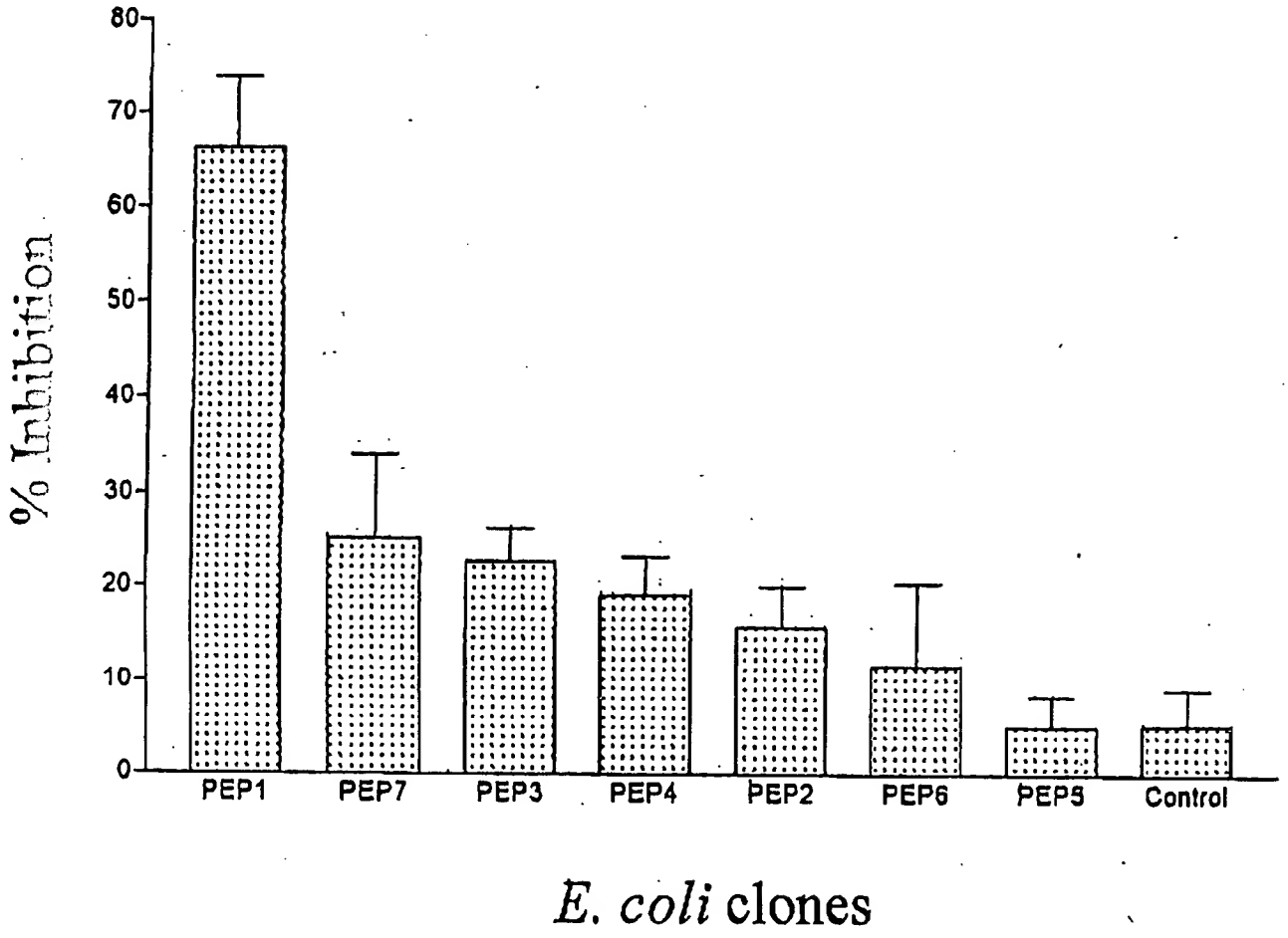
Book 4
100 sheets • 200 pages
9¾ x 7½ in/24.7 x 19.0 cm
wide ruled • 09910
© 1987—The Mead Corporation, Dayton, Ohio 45463 U.S.A.

Figure 7.

Inhibition of mAb 2C7 binding to LOS by *E. coli* clones expressing peptide fusions



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Group Art Unit	:	1645
Examiner	:	S. Devi

New York, New York
August 26, 2003

Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION OF PETER A. RICE UNDER 37 C.F.R. § 1.132

I, PETER A. RICE hereby declare and state as follows:

1. I am one of the co-inventors of the subject matter of the above-identified application.

2. I am currently Chief of the Section of Infectious Diseases of Boston Medical Center, 650 Albany Street, Boston, MA. I have held this position since 1996.

3. I received an M.D. in 1969 from the University of Pennsylvania School of Medicine. I completed my residency in 1974 at Peter Brigham Hospital. From

1974-1977 I held a clinical fellowship in Infectious Diseases at Harvard Medical School. I have published over 50 scientific papers in peer-reviewed journals in the relevant field of research. A copy of my curriculum vitae is attached as Exhibit A.

4. A major portion of my clinical research over the past twenty years has been devoted to the pathogenesis of gonococcal infection and host response of patients afflicted with *Neisseria gonorrhoeae* infection. Publications pertaining to my research may be found listed in my curriculum vitae (Exhibit A).

5. I am informed and believe that certain claims in the above-identified application have been rejected based upon United States patents 5,476,784 ("'784 patent"); 5,939,067 ("'067 patent") and 6,099,839 ("'839 patent"), collectively, "the three patents." In particular, I understand that the Examiner believes that certain of the peptide mimics claimed in the present application are unpatentable under the judicially created doctrine of obviousness-type double patenting over the three patents, anticipated under 35 U.S.C. § 102(e) by the '869 patent, anticipated under 35 U.S.C. § 102(e) or 102(a) by the '067 patent, anticipated by the '784 patent under 35 U.S.C. § 102(b) and/or obvious under 35 U.S.C. § 103(a) over the '784 patent.

6. I make this declaration in support of the Reply to Office Action and Amendment, filed herewith in response to the February 26, 2003 Office action received in the above-identified application.

7. Specifically, I make this declaration in support of applicants' argument that the claimed subject matter of the present application is patentably distinct from the subject matter of the three patents.

8. In rejecting the pending claims, it appears that the Examiner is under the impression that the peptide mimics of the present invention were derived from

the anti-idiotypic antibodies of the three patents, and that the claimed peptide mimics have essentially the same properties of fragments of anti-idiotope antibodies discussed in the three patents.

9. This is not the case. The peptide mimics of the instant invention were generated by a selection method from a commercially available peptide library (*See* specification, *e.g.*, page 12, line 28 to page 13, line 8). Therefore, the claimed peptide mimics have a derivation independent of the anti-idiotype antibodies disclosed in the three patents.

10. The three patents do not teach or suggest the peptide mimics described in the instant invention, nor do they refer to the use of any peptide mimics in the prevention or treatment of *N. gonorrhoeae* infections. The term "fragments" is defined in the '784, '067 and '839 patents as "portions of intact immunoglobulins that retain antigen binding specificity, for example, Fab fragments, Fab' fragments, $F(ab')_2$ fragments and F(v) fragments, fragments comprised of one or more complementarity determining region(s) (CDR), heavy chain monomers or dimers, light chain monomers or dimers, dimers consisting of one heavy and one light chain, and the like" (*See, e.g.*, '784 patent column 5, lines 30-37).

11. In contrast, applicants' claimed peptide mimics are not portions of intact immunoglobulins. Furthermore, one of ordinary skill in the art as of the filing date understood that the fragments described in the three patents typically contain at least 50 amino acid residues. In the instant application, the claimed peptide mimics are defined as linear or cyclic chains of amino acids, usually at least 4 and less than 50 amino acids in length, which exhibit an immunological antibody binding profile similar to that of a

known epitope (*See, e.g.*, specification at page 12, lines 1-6). The three patents do not discuss or even mention such peptide mimics.

12. Moreover, it can be seen that the structure of the peptide mimics of the instant invention is distinct from the structure of the anti-idiotypic antibodies of the three patents. Attached hereto as Exhibit B are data showing the alignment of the amino acid sequence of one of the claimed peptide mimics of the instant invention, PEP1, with the sequences of the variable heavy and light chain subunits of the CA1 anti-idiotypic antibody discussed in the three patents. These variable heavy and light chain subunit sequences are the sequences that would be expected to be functionally analogous to the sequences of the instantly claimed peptide mimics. Using the BLAST sequence alignment program (http://www.ncbi.nlm.gov), it can be seen that there is no significant homology between the amino acid sequence of PEP1 and the CA1 anti-idiotypic antibody variable subunits. This demonstrates that the instantly claimed peptide mimics are structurally distinct from fragments of anti-idiotypic antibodies of the three patents.

13. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Peter A. Rice

Peter A. Rice, M.D.

Signed this 19th day of

August, 2003 at Boston, Massachusetts.

EXHIBIT A

7/08/03

Curriculum Vitae

Peter Alan Rice

Address: Evans Biomedical Research Center
Boston Medical Center
650 Albany Street
Boston, Massachusetts 02118 Work: 617-414-5282
617-414-5280 (fax)
parice@bu.edu (e-mail)

55 Norfolk Road
Chestnut Hill, Massachusetts 02467 Home: 617-738-6032

Date of birth: May 25, 1942

Place of birth: Orange, New Jersey

Education:

1964	B.E.(Engineering)	Yale University, New Haven, Connecticut.
1965	Special Student	Yale University
1969	M.D.	University of Pennsylvania, Philadelphia, Pennsylvania.

Medical School Training Appointments:

1967 (Summer) Trainee in Anesthesiology, Appointed by the American Society of Anesthesiology, Mayo Clinic, Rochester, Minnesota.

1968 (Summer) Clinical Clerk in Medicine, Western General Hospital, University of Edinburgh, Edinburgh, Scotland.

Post-doctoral Training

Internship and Residences:

1969-70 Intern in Medicine, Department of Medicine, Yale-New Haven Hospital, New Haven, Connecticut.

1970-71 Assistant Resident in Medicine, Department of Medicine, Yale-New Haven Hospital, New Haven, Connecticut.

1973-74 Senior Resident Physician, Department of Medicine, Peter Bent Brigham Hospital, Boston, Massachusetts.

5/30/03

Curriculum Vitae

Peter Alan Rice

Address: Evans Biomedical Research Center
Boston Medical Center
650 Albany Street
Boston, Massachusetts 02118 Work: 617-414-5282
617-414-5280 (fax)
parice@bu.edu (e-mail)

55 Norfolk Road
Chestnut Hill, Massachusetts 02467 Home: 617-738-6032

Date of birth: May 25, 1942

Place of birth: Orange, New Jersey

Education:

1964	B.E.(Engineering)	Yale University, New Haven, Connecticut.
1965	Special Student	Yale University
1969	M.D.	University of Pennsylvania, Philadelphia, Pennsylvania.

Medical School Training Appointments:

1967 (Summer) Trainee in Anesthesiology, Appointed by the American Society of Anesthesiology, Mayo Clinic, Rochester, Minnesota.

1968 (Summer) Clinical Clerk in Medicine, Western General Hospital, University of Edinburgh, Edinburgh, Scotland.

Post-doctoral Training

Internship and Residences:

1969-70 Intern in Medicine, Department of Medicine, Yale-New Haven Hospital, New Haven, Connecticut.

1970-71 Assistant Resident in Medicine, Department of Medicine, Yale-New Haven Hospital, New Haven, Connecticut.

1973-74 Senior Resident Physician, Department of Medicine, Peter Bent Brigham Hospital, Boston, Massachusetts.

Clinical and Research Fellowships:

1970-71 Teaching Fellow in Medicine, Yale University School of Medicine, New Haven, Connecticut.

1973-74 Clinical Fellow in Medicine, Department of Medicine, Harvard Medical School, Boston, Massachusetts.

1974-76 Research Fellow in Medicine, Department of Medicine, Channing Laboratory, Harvard Medical School, Boston, Massachusetts.

1974-75 Clinical Fellow in Medicine, Boston City Hospital, Boston, Massachusetts.

Sabbatical

1989 Visiting Scientist, Molecular Biology Institute, University of California at Los Angeles (UCLA) - Sherie L. Morrison, Ph.D.

Licensure and Certifications:

1970 National Board of Medical Examiners (Diplomate) Registration No. 107460

1974 Massachusetts License, Registration No. 37191

1974 American Board of Internal Medicine, Candidate No. 04571.

1976 American Board of Internal Medicine (Infectious Disease) Candidate No. 04571.

Academic Appointments:

1976-77 Instructor, Department of Medicine, Channing Laboratory, Harvard Medical School, Boston, Massachusetts.

1977-81 Assistant Professor of Medicine, Department of Medicine, Boston University School of Medicine, Boston, Massachusetts.

1981-88 Associate Professor of Medicine, Department of Medicine, Boston University School of Medicine, Boston, Massachusetts.

1984- Associate Professor of Microbiology, Department of Microbiology, Boston University School of Medicine, Boston, Massachusetts.

1985- Associate Professor, Division of Graduate Medical Sciences, Boston University Gradua School, Boston, Massachusetts.

1988- Professor of Medicine, Department of Medicine, Boston University School of Medicine, Boston, Massachusetts.

1988- Professor of Public Health (Environmental Health), Boston University School of Public Health, Boston, Massachusetts.

Academic Appointments, cont'd.

1990-95	Co-Director, Infectious Diseases, Boston University School of Medicine, Boston, Massachusetts.
1995-96	Director (Interim), Infectious Diseases, Boston University School of Medicine
1996 -	Chief, Section of Infectious Diseases, Boston Medical Center, Boston University School of Medicine
1997 -	Faculty Appointments and Promotions Committee, Boston University School of Medicine

Hospital Appointments:

1975-83	Assisting Visiting Physician, Medical Service, Boston City Hospital, Boston, Massachusetts.
1977-96	Associate Staff, Medicine (Infectious Diseases), University Hospital, Boston, Massachusetts.
1983-88	Associate Visiting Physician, Medical Service, Boston City Hospital, Boston, Massachusetts.
1988-96	Visiting Physician, Medical Service, Boston City Hospital, Boston, Massachusetts.
1990-00	Director, The Maxwell Finland Laboratory for Infectious Diseases
1995-	Active Staff Member, Jewish Memorial Hospital, Boston, Massachusetts
1996-	Active Staff Member, Boston Medical Center, Boston, Massachusetts

Hospital Service Appointments (Boston City Hospital [now Boston Medical Center]):

Associate Director

1977-90	The Maxwell Finland Laboratory for Infectious Diseases, Boston City Hospital
1990-93	Division of Clinical Laboratories, Boston City Hospital

Director

1977-92	Clinical Immunology Laboratory
1984-85	Allergy Clinic
1985-86	Infectious Disease Consult Clinic
1986-88	Sexually Transmitted Disease Clinic (Co-Director)
1990-96	Chief of Infectious Diseases, Boston City Hospital and Director, The Maxwell Finland Laboratory for Infectious Diseases
1993-94	Sexually Transmitted Disease Clinic (Co-Director)
1994-99	Sexually Transmitted Disease Clinic

Committees (*ad hoc* committees [eg. search committees] not listed)

1981-88	Library Committee
1983-93	Laboratory Advisory Committee

1988-89	Department of Medicine Task Force on AIDS
1988-89	Department of Medicine Planning Group
1990	Medical Executive Committee (as representative for Medical subspecialties)
1990	Credentials Committee
1995-96	Medical Directors Group, Ambulatory Care Center (ACC) Clinics, Boston City Hospital
1995	Policy Committee, Trustees of Health and Hospitals of the City of Boston, Inc.

Other Professional Positions Held:

1971-73	United States Public Health Service, Epidemic Intelligence Service (EIS) Officer, Center for Disease Control, Epidemiology Program, Bacterial Disease Branch, Enteric Disease Section, Atlanta, Georgia.
1975-78	Attending Physician in Medicine, South End Community Health Center, Boston, Massachusetts.
1977	Consulting epidemiologist, Wrentham State School, Wrentham, Massachusetts.
1977-85	Associate Staff, Dana Farber Cancer Institute, Boston, Massachusetts.
1983-84	Acting Director, The Maxwell Finland Laboratory and Section of Infectious Diseases at Boston City Hospital.
1996-00	Member, Evans Medical Foundation Board of Directors
1996-	Steering Committee for PROCAARE, The Program for Collaboration Against AIDS and Related Epidemics (Global Communications for Health)

Awards and Honors:

1964	Ranking scholar, Yale School of Engineering.
1969	Roche Award (Gold Watch) - Awarded to the member of the graduating class whose qualifications exemplify those of the ideal American physician.
1978-	National Institutes of Health research grant awardee
1978,79	Biomedical Research Grant Support (BRSG) awardee
1979-82	Charles H. Hood Foundation grant awardee
1988-93	Centers for Disease Control and Prevention (CDC) research grant awardee
1998-	Centers for Disease Control and Prevention (CDC) research grant awardee

Membership in Professional Societies

American Federation for Clinical Research, Councillor, Eastern Section, 1979-81
Infectious Disease Society of America; Fellow.
American College of Physicians; Fellow.
American Society for Microbiology
American Sexually Transmitted Disease Association
American Association for the Advancement of Science
Massachusetts Infectious Disease Society, Councilor, 1992-94

Scientific Committees

National Institutes of Health (Charter Memberships [*ad hoc* assignments not listed])

1985-89	Bacteriology and Mycology Study Section, No. 2, (BM2) National Institute of Allergy and Infectious Diseases.
1991-95	Microbiology and Infectious Disease Research Committee (MIDRC), National Institute of Allergy and Infectious Diseases.
1995-99	National Institutes of Health Reviewers Reserve (NRR).

1980-90 Scientific Advisory Board, Hygeia Sciences, New[redacted] Massachusetts.

1980-94 Scientific Advisory Review Committee (SARC) for Biomedical Research Grant Support (BRSG), Trustees of Health and Hospitals of the City of Boston, Boston, Massachusetts; Chairman; 1983-1994.

1995-00 Scientific Advisory Board, Binax Laboratories, Portland, ME

1995-00 (PEACH) Study – PID Evaluation and Clinical Health Study, Data Safety Monitoring Board, University of Pittsburgh

2000- Syphilis Treatment Trial Data Safety Monitoring Board, STD Branch, NIH/NIAID

2000-01 STD Treatment Guidelines Committee, Centers for Disease Control and Prevention

2000 Co- chair, International Pathogenic Neisseria Conference, Galveston, TX

2001 Consultation on the Control of *Neisseria gonorrhoeae* Infection in the United States, Moderator: Gonorrhea control among special populations, Centers for Disease Control and Prevention

Editorial Board

1986-99 Sexually Transmitted Diseases

Editorial Consultant, 2001-2002

New England Journal of Medicine
Journal of Endotoxin Research
Clinical Infectious Diseases
Journal of Infectious Diseases

Major current research interests:

1. Immunology of bacterial infection
   a. Immunology and pathogenesis of human infection with *Neisseria gonorrhoeae*
      (1) Role of lipo-oligosaccharides (LOSs) and LOS derived oligosaccharides in promoting inflammation via complement-dependent antibody activity
      (2) Mechanisms of complement activation (and inactivation) in gonococcal infection.
      (3) Immunochemical studies of outer membrane proteins; their roles and those of antibodies directed against them in promoting gonococcal infection.

   b. Immunology of infection with non-typable (NT) *Haemophilus influenzae*
      (1) Immunochemical and biochemical studies of outer membrane proteins and antibodies directed against them that protect against mucosal infections in humans.
      (2) Experimental models of NT *H. influenzae* infection
      (3) Evolutionary relatedness (by ribosomal typing) of NT *H. influenzae* in predicitin homo-/heterogeneity of vaccine candidates at the molecular level.

2. Bacterial immunochemistry
   a. Development of monoclonal antibody reagents against bacterial species specific membrane antigens for use in the diagnosis of human infection.

   b. Studies of bacterial antigens their anti-idiotope surrogates and peptides mimicking lipooligosaccharide epitopes for human immmunoprophylaxis.

3. Epidemiology of bacterial infections
   a. Epidemiology of sexually transmitted diseases (STDs).
      (1) Microbial and behavioral risk factors associated with transmission of *Chlamydia trachomatis* in adolescents.
      (2) Optimizing strategies to provide STD partner services and reduce repeat infections in index cases.
      (3) Pelvic inflammatory disease caused by *N. gonorrhoeae* and *C. trachomatis*, particularly silent disease.
      (4) Disseminated gonococcal infection.
      (5) Influence of immune mechanisms on the transmission and epidemiology of *N. gonorrhoeae* and *C. trachomatis* infection.
      (6) Behavioral strategies to prevent transmission of sexually transmitted diseases (STDs).

4. New antimicrobial therapies for the treatment of STDs

Teaching Appointments:

1975-	Attending physician (Internal Medicine), In patient service, Boston City Hospital, (now Boston Medical Center) Boston University School of Medicine, Boston, MA
1976-87	Attending physician (Infectious Diseases), Dana Farber Cancer Institute, Harvard Medical School, Boston, MA
1977-84, 1994-00	Lecturer, Medicine 513MJ, Infectious Diseases, Harvard Medical School, Boston, MA.
1977-91, 1995-00	Lecturer and Laboratory Instructor, MED ME 711 (currently GMS MI 711) Microbiology Course, Boston University School of Medicine, Boston, MA.
1977-	Infectious Disease Teaching Consultant, Teaching hospitals of Boston University School of Medicine; Boston Medical Center (formerly Boston City and University Hospitals).

Trainees (Masters' students not a):

Post-doctoral fellows*	Dates	Current position
Steven L. Berk, MD (10,18)	1977-1979	Dean of Texas Tech School of Medicine in Amarillo
James P. O'Brien, MD (16,23,37,48)	1979-1981	Staff Physician, Alexian Brothers Hospital, Elk Grove Village, Illinois
Hanspeter E. Gnehm, MD (32,33)	1980-1982	Chief of Pediatrics,Kinderlink, Kantonsspital, Zurich, Switzlerland
Francisco J. Alvarado, MD [A-59,-61,-71,-72]	1984-1988	Chief, Geographic Medicine General Hospital, Cancun, Mexico
Peter A. Dale, MD (29,45,51,69)	1986-1988	Private Practice in Internal Medicine & Infectious Diseases, Central Vermont Medical Center
S. Patrick Donegan, MD (70,81,91)	1986-1988	Staff Physician, OB/GYN Department ASPEN Medical Group, Minnesota
Daniel P. McQuillen, MD (63,69,74,77)	1988-1991	Staff Physician Lahey Clinic, Burlington, MA
Sunita Gulati, DSc (77,78,82,90,93-95)	1993-1998	Research Assistant Professor of Medicine Boston University of Medicine
Sanjay Ram, MD (94,95,99,101)	1994-1998	Assistant Professor of Medicine, Boston University School of Medicine
Phillip G. Braslins, MD [A-144,-163,-164,-165]	1997-2000	Assistant Professor of Medicine (pending) Boston University School of Medicine
Guillermo E. Madico, MD, PhD	2000-2001	Postdoctoral Fellow, Boston University School of Medicine
Katherine Hsu, MD	2001-	STD Prevention Fellow, Association of Teachers of Preventative Medicine (ATM)/Centers for Disease Control and Prevention (CDC)
Alpana Prasad, PhD	2001-	Postdoctoral Fellow, Boston University School of Medicine
Jutamas Ngampasutadol, MD, PhD	2002 -	Postdoctoral Fellow, Boston University School of Medicine

* Under direct supervision, participated in creative works (publication [or abstract] numbers) during period as a post-doctoral fellow and, if published later, from work during the post-doctoral fellowship period

Doctoral Students*

Deyanira D. Garcia, PhD 1987-1990
Thesis title:-Purification, partial characterization,and immuno-reactivity of a 60 kDa *Brucella melitensis* B115 outer membrane protein, [A-61, A-71, A-72, A-73] (PhD awarded by School of Biologic Sciences, the National Polytechnical Institute, Mexico, DF, Mexico - 1995)

Sunita Gulati, DSc 1988-1993
Thesis title:- Anti-idiotope antibody as a surrogate vaccine immunogen for lipooligosaccharide (LOS) of *Neisseria gonorrhoeae* (52,62,69,74,80,88,89)

Gilles R. Bolduc, PhD 1991-1998
Thesis title: Combining phylogeny and selective DNA sequencing to examine a vaccine candidate (105)

Silke Getzlaff 1999- present (completing medical studies at Univ.Wurzburg)
Thesis title [proposed]: The role of capsule in complement interactions with meningococci of different groups. [A-154, A-157-159]

Jutamas Ngampasutadul, MD , PhD 1996-2002
Thesis title: Peptide mimic elicits bactericidal antibody response against an oligosaccharide epitope of *Neisseria gonorrhoeae* (111)

Invited lectureships at national and international conferences; those published as abstracts are listed ahead in **ABSTRACTS (invited speaker).** Visiting professorships and Grand Rounds presentations are not listed.

The functional roles of human antibodies directed against outer membrane antigens of *Neisseria gonorrhoeae*. Third International Pathogenic Neisseria Conference, Montreal, Canada, August 1982.

Immunologic features of LPS and LPS derived oligosaccharides: their interaction with naturally occurring antibodies and their potential for immunogenicity. Workshop of "newer" aspects in the development of a vaccine for gonorrhea. National Institutes of Health, Bethesda, MD, January, 1983.

Acute Pelvic Infection. International Meeting of Maternal-Child Health Care. Mexico City, Mexico, May,1984.

Recent Advances in Gonococcal Infection. International Meeting of Maternal-Child Health Care. Mexico City, Mexico, May, 1984.

Interactions of antibodies and complement on bacterial surfaces: lessons learned from the gonococcus. Tenth International Convocation on Immunology. Vaccines: New Concepts and Developments, Buffalo, New York, June, 1986.

Mechanism of stable serum-resistance of *Neisseria gonorrhoeae.* Fifth International Pathogenic Neisse Conference, Noordwijkerhout, The Netherlands, October, 1986

* Under direct supervision, participated in creative works (publication [or abstract] numbers) during period as a graduate student and, if published later, from work during the pre-doctoral student period

Competition of antibod[redacted]and complement on bacterial surfaces - the gonococcal paradigm. 27th Interscience Conference of Antimicrobial Agents and Chemother[redacted], October, 1987.

Serum-Resistance of *N. gonorrhoeae*: Molecular basis. Sixth International Pathogenic Neisseria Conference, Atlanta, Georgia, No. MT2, October, 1988.

Specific roles of antibodies and complement in serum killing of *Neisseria gonorrhoeae*. American Society for Microbiology, New Orleans, Louisiana, May, 1989.

Blocking antibodies as they affect the immune system. Merck Sharp & Dohme Health Science Associate Infectious Disease Fellows Symposium, Albuquerque, New Mexico, August, 1990.

Neisseria gonorrhoeae employ diverse strategies to evade humoral host defenses. 31st Interscience Conference on Antimicrobial Agents and Chemotherapy, October, 1991.

Immunopathology of Gonorrhea. The Molecular Immunology of Sexually Transmitted Diseases. Sponsored by NIAID National Vaccine Program, Centers for Disease Control Food and Drug Administration and Department of Defense, Rocky Mountain Laboratories, Hamilton, Montana, July, 1991.

Antibodies, Microbes and Complement. Third Conference on Microbial Virulence Factors and the Human Immune Response. Oakland, CA September,1991.

The male to female transmission of *Neisseria gonorrhoeae* is influenced by level of antibody to gonococcal Protein III. Eighth International Pathogenic Neisseria Conference, Mexico, October, 1992.

Pelvic inflammatory disease and prospects for a gonococcal vaccine. Infectious Disease '92; Life-Time Medical Television, Aired September 20, October 11, November 1, and 22, 1992.

Serum resistance of *Neisseria gonorrhoeae*: Does it thwart the inflammatory response and facilitate the transmission of infection? Microbial Pathogenesis and Immune Response. Sponsored by the NY Academy of Sciences, Orlando, FL, September, 1993.

Male Genitourinary Infections. Workshop on Ligase Chain Reaction (LCR) From Research to Clinical Laboratories. Sponsored by Abbott LCX Probe System, Taormina, Sicily, June, 1994.

A possible influence of vaccine induced Por, LOS, and Rmp antibodies on the outcome of intraurethral challenge with *Neisseria gonorrhoeae*. Ninth International Pathogenic Neisseria Conference, Winchester, England, September, 1994.

Immunologic and Microbiologic factors responsible for transmission of *Neisseria gonorrhoeae* and *Chlamydia trachomatis*. Workshop on Pelvic Inflammatory Disease. National Institute of Allergy and Infectious Diseases, Bethesda, Maryland, December, 1994.

Transmission of Gonorrhea and Chlamydial Infection from Men to Women: Efficiency and Sequelae. Sexually Transmitted Diseases in the HIV Era, Keystone, Colorado, April, 1995.

Is there protective immunity to gonococcal disease? 10th Internat Pathogenic Neisseria Conference, Baltimore, Maryland, September 8-13, 1996.

A Randomized trial of Ceftriaxone and Doxycycline vs. Ofloxacin and Clindamycin in the treatment of Sexually Acquired Plasma Cell Endometritis. The 12th Meeting of the International Society of Sexually Transmitted Diseases Research (ISSTDR), Seville, Spain, October 19-22, 1997.

Infection in the upper genital tract: Does Chlamydia prevail persist and contribute to prolonged morbidity., Annual Meeting of the Swiss Society of Obstetrics and Gynecology, Geneva, Switzerland, June 17-20, 1998.

Interaction of *N. gonorrhoeae* lipooligosaccharide (LOS) and complement in the genital tract. The fifth conference of the International Endotoxin Society, Santa Fe, NM, September 12-15, 1998.

Pelvic Inflammatory Disease: Shortcomings in Recognition, Complications and Management, Where do we go from here? Current Topics in Infectious Diseases, Bermuda, April 16-18, 1999.

Complement and the Gonococcus; Does Innate Immunity Matter? Twelfth International Pathogenic Neisseria Conference, Galveston, TX, November 13-17, 2000.

How Pathogenic Neisseria Differ When Confronted by Complement. Fifteenth Annual Buffalo Conference on Microbial Pathogenesis, Microbial Pathogenesis Graduate Group & The Western New York Of The American Society For Microbiology, Amherst, NY, April 30, 2003

Personal

Spouse	Nancy Royster Rice, married August 22, 1965.
Daughter	Nicole Randolph Rice, born October 11, 1973.

External funding support for research and clinical programs, Peter A. Rice, M.D., Principal Investigator

Current Support (Direct cost support for the current Fiscal Year [2003-04]

+1. Cooperating clinic for sexually transmitted diseases (07/01/02 – 6/30/04) $254,959. P.A. Rice, M.D. - Principal Investigator. Source - Commonwealth of Massachusetts, State Laboratory.

*2. Program Announcement 98094 (10/01/98-09/30/03 Measuring the Risk for Transmission and Sequelae from Chlamydial Disease in the Era of Amplification Testing, $275,393. P.A. Rice, MD - Principal Investigator. Source - Centers for Disease Control and Prevention (CDC).

*3. RO1 AI 32725-07 (04/01/99-03/31/09). Immunology of Infection with *Neisseria gonorrhoeae,* $293,625. P.A. Rice, M.D. - Principal Investigator. Source - National Institutes of Health.

*4. U19 AI 38515-07 (09/30/99 – 08/31/04). Sexually Transmitted Disease Coop. Research Center, $691,820. P.A. Rice, MD. - Principal Investigator. Source – National Institutes of Health.

*5. RO1 AI 44151-02 (04/01/99 – 11/30/03). Gyn Infection Follow Through (GIFT) Study, Roberta Ness, MD – Principal Investigator. Source – National Institutes of Health. Sub-contract, $31,204. P.A. Rice, M.D., Co-I.

*6. PO1 AI 46518 (12/01/99 – 05/31/05). Immunity to STDs in the Human Male Genital Tract, Deborah Anderson, MD – Principal Investigator. Source – National Institutes of Health. Sub-contract, $31,109. P.A. Rice, M.D., Co-I.

*7. Program Announcement 00080 (9/30/00 – 9/29/04). Optimizing Strategies to Provide Sexually Transmitted Diseases (STD) Partner Services, $269,048. P.A. Rice, MD - Principal Investigator. Source - Centers for Disease Control and Prevention (CDC).

♦8. T32 AI52070-01 (07/01/02 – 06/30/07). Training Program in Host Pathogen Interactions, $119,400. Peter A. Rice, MD – Principal Investigator. Source – National Institutes of Health

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+ Clinical Service
* Research
♦ Training

Past Support (Direct costs total [redacted] $18,507,621)

1. RO1 AI 15633. Immunology of Infection with *Neisseria gonorrhoeae*, $701,200. (12/01/78-11/30/88). Source - National Institutes of Health.

2. Immunologic and Chemical Studies of Non-Typable *Haemophilus influenzae* in children with Otitis Media, $55,902, (08/01/79-06/30/82). Source - Charles H. Hood Foundation.

3. Immunochemical Studies of Infection with *Neisseria gonorrhoeae*, $3,958, (08/01/78-07/31/79). Source - Biomedical Research Support Grant.

4. Immunochemical Studies of Non-Typable *Haemophilus influenzae* in children with Otitis Media, $3,000, (08/01/79-07/31/80). Source - Biomedical Research Support Grant.

5. Purification of 19,000 M.W. Common Antigen from *Neisseria gonorrhoeae*, $20,241, (01/01/85-12/31/85). Source - Hygeia Sciences, Newton, MA.

6. Clinical Testing of Dupont's new test procedure for the direct detection of *N. gonorrhoeae* from urogenital secretions, $47,207, (01/01/85-12/31/85). Source - E.I. DuPont de Nemours & Co.

7. IM Cefmetazole (U-72791A), Cefoxitin or Penicillin for the Treatment of Uncomplicated Gonococcal Infections, $146,000, (01/17/87-05/18/89). Source - Upjohn Pharmaceutical Co., Kalamazoo, MI.

8. Passive immunization of chinchillas with antibody directed against NT *H. influenzae* Protein 6 to prevent otitis media, $6,598, (07/01/87-06/30/88). Sources - Praxis Biologics, Rochester, N.Y.

9. Treatment of Nongonococcal Urethritis in Males with Intramuscular Trospectomycin Sulfate, $22,880, (03/01/88-06/21/88). Source - Upjohn Pharmaceutical Co., Kalamazoo, MI

10. RO-6240 (Fleroxacin) in the Treatment of Uncomplicated Gonorrhea: A Randomized, Open Study Versus Ceftriaxone, $44,245, (08/23/88-07/10/89). Source - Roche Pharmaceuticals, a division of Hoffmann-La Roche, Nutley, NJ).

11. Development of rapid tests for sexually transmitted diseases, $367,359, (6/01/83-7/23/90). Source - Hygeia Sciences, Newton, MA.

12. Cooperating clinic for sexually transmitted diseases, $2,510,642 (07/01/86-07/23/97). Commonwealth of Massachusetts, State Laboratory.

13. Development of a culture facility for *Chlamydia trachomatis*, $225,819, (08/01/86-06/30/90). Source - Hygeia Sciences, Newton, MA.

14. Comparison of Oral Cefpodoxime Proxetil (U-76252) and Ceftriaxone in the Treatment of Uncomplicated Gonococcal Infection, $17,157, (01/04/90-05/07/90. Source - The Upjohn Company, Kalamazoo, MI.

15. Treatment of Gonococcal Infections with Intramuscular Trospectomycin Sulfate (U-63,366F) or Ceftriaxone Sodium (Rocephrin), $21,475, (0[redacted]/89-03/06/90). Source - The Upjohn Company, Kalamazoo, MI.

16. 1 PO1 NS21914-ID #032-30-2447. Clinical Otolaryngologic Research Center. Source - National Institutes of Health (NIND-CD) (09/01/85-08/31/90). Gerald B. Healy, M.D. - P.I.

    Subproject: Experimental models of bacterial Otitis Media, $390,921, (12/01/85-12/31/90). PI's - S.I. Pelton, M.D. and P.A. Rice, M.D.

17. Azithromycin in the Treatment of Chlamydial Urethritis/Cervicitis; A Multicenter Comparative Trial", $12,000, (07/01/90-12/31/90). Source - Pfizer, Inc.

18. Clinical Investigation of PB Diagnostic Systems, Inc. **OPUS** ™ HIV 1+2 Test System, $29,618, (07/01/90-08/31/91). Source - PB Diagnostics.

19. A Multicenter Open Comparative Trial of Azithromycin and Ceftriaxone in Patients with Uncomplicated Gonococcal Urethritis/Cervicitis, $128,250, (10/01/90-09/30/91). Source - Pfizer, Inc.

20. Ciprofloxacin vs. Standard Antibiotic Therapy, $6,600, (02/01/91-07/31/91). Source - Parexel International Corporation..

21. Diagnostic Testing for *N. gonorrhoeae*, $13,500, (05/01/91-09./30/91). Source - Unipath Limited.

22. PO1 AI 24760. Clinical and Laboratory Studies of Pelvic Inflammatory Disease (PID), $2,384,935, (06/01/87-05/31/92). P.A. Rice, M.D. - Principal Investigator; Source - National Institutes of Health.

23. An Open-Label Multi-Investigator Comparative Study of the Safety and Efficacy of Cefepime and Ceftazidime in the Treatment of Hospitalized Patients with Septicemia, $2,000 (05/01-07/31/92). P.A. Rice, M.D., Co-Principal Investigator. Source - Bristol Myers.

24. The Alternative Test Site Program for HIV Antibody Testing, $129,823. (07/01/91-12/30/93). P.A. Rice, M.D. - Principal Investigator. Source - Commonwealth of Massachusetts, State Laboratory.

25. RFP 200-88-0649. Sentinel Hospital Surveillance System for HIV Infection, $420,030 (10/01/88-9/30/93). P.A. Rice, M.D. - Principal Investigator. Source - Centers for Disease Control and Prevention.

26. Study of Ceftin for treatment of *N. gonorrhoeae* (75 evaluable patients), $79,500 (07/01/92-06/30/93). P.A. Rice, M.D., Co-Principal Investigator. Source - Glaxo Pharmaceuticals.

27. Pre-Clinical Evaluation of HBsAg, $7,445 (07/01/92-06/30/93). P.A. Rice, M.D., Principal Investigator. Source - PB Diagnostic Systems, Inc.

28. NO1-AI82507. Collaborative Prospective Cohort Studies of Perinatal Transmission of HIV and Retroviral Infections, $535,244 - Core Laboratory (07/01/89-06/30/93). Ruth Tuomala, M.D. - Principal Investigator. Source - National Institutes of Health.

29. New pharmaceutical agent for treatment of gonorrhea and chlamydia infection, $81,428 (07/01/94-06/30/95). P.A. Rice, M.D. - Principal Investigator. Source - Otsuka.

30. PO1 AI 33087 (09/01/92-04/30/96). Clinical and Laboratory Studies of PID, $2,503,011. P.A. Rice, M.D. - Principal Investigator. Source - National Institutes of Health.

31. REP 200-93-0622 (09/27/93-06/30/96). Sentinel Hospital Surveillance for HIV infection, $334,348. P.A. Rice, M.D. - Principal Investigator. Source - Centers for Disease Control and Prevention.

32. A Randomized, Multicenter, Double-Blind, Double Dummy Comparative Study of CP-99,219 and Doxycycline for the treatment of Uncomplicated Chlamydial Urethritis/Cervicitis (07/01/95-06/30/96). $31,320. P.A. Rice, M.D. - Principal Investigator. Source - Corning Besselaar, Inc.

33. UO1 AI 34856 (07/01/93-06/30/97). Collaborative Prospective Cohort Studies of Perinatal Transmission of HIV and Retroviral Infections. Ruth Tuomala, M.D. - Principal Investigator. Source - National Institutes of Health.
**Core laboratory, $323,512. P.A. Rice, M.D., P.I.

34. A Randomized, Double-Blind, Multicenter, Phase III Study of Two Single Dose Regimens of Gatofloxacin and a single dose of Ofloxacin in the treatment of Uncomplicated Gonococcal Infections. (01/01/98 – 05/01/98). $20,000. Peter A. Rice, Principal Investigator; Source – Bristol-Myers Squibb Company.

35. RO1 AI 32725 (01/01/93-12/31/97). Immunology of Infection with *Neisseria gonorrhoeae*. $894,972. Peter A. Rice, MD – Principal Investigator. Source – National Institutes of Health.

36. A Prospective Randomized Open-Label Study to Treat Silent Endometritis, (10/01/95-06/30/98) $217,800, P.A. Rice, M.D. - Principal Investigator. Source - Ortho-McNeil Pharmaceuticals.

37. U19 AI 38515 (07/01/95-06/30/99). Sexually Transmitted Disease Coop. Research Centers, $5,152,315. P.A. Rice, M.D. - Principal Investigator. Source - National Institutes of Health.

38. The Factive™ Study to treat Chlamydial and Non-gonococcal Urethritis, (06/01/99 – 10/31/99) $19,500,. P.A. Rice, M.D. - Principal Investigator. Source – Smith Kline and Beecham Pharmaceuticals, Collegeville, PA.

39. Cobas Amplicor *Chlamydia trachomatis* Clinical Trial, (1999-2001) $50,000., P.A. Rice, MD. – Principal Investigator. Source – Hoffmann-La Roche, Inc.

40. U01 AI 39226-05 (10/01/95-09/30/00). STD Diagnostic Development Group. Roger N. Piasio - Principal Investigator. Source - National Institutes of Health.
Sub-contract, $541,866. P.A. Rice, M.D., P.I.

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2. Weissman, JB, **Rice, PA**, Krogstad, DJ, Baine, WB, and Gangarosa, EJ. Risk of severe intestinal infection to the traveler in Mexico. J. Infect. Dis. 128: 574-578, 1973.

3. Levine, MM, **Rice, PA**, Gangarosa, EJ, Morris, GK, Snyder, MJ, Formal, SB, Wells, JB, and Hammond, J. An outbreak of Sonne Shigellosis in a population receiving oral attenuated shigella vaccines. Amer. J. Epid. 99: 30-36, 1974.

4. **Rice, PA**, Craven, PC, and Wells, JG. *Salmonella heidelberg*, enteritis and bacteremia: an epidemic on two pediatric wards. Amer. J. Med. 60: 509-516, 1974.

5. Kasper, DL, **Rice, PA**, and McCormack, WM. Bactericidal antibody in genital infection due to *Neisseria gonorrhoeae*. J. Infect. Dis. 135: 243-251, 1977.

6. Baine, WB, Farmer, JJ, Gangarosa, EJ, Hermann, G, Thomsberry, C, and **Rice, PA**. Typhoid in the United States associated with the 1972-73 epidemic in Mexico. J. Infect. Dis. 135: 49-53, 1977.

7. **Rice, PA**, Baine, WB, and Gangarosa, EJ. *Salmonella typhi* infection in the United States, 1967-72: Increasing importance of foreign travelers. Amer. J. Epid. 106: 160-166, 1977.

8. **Rice, PA**, and Kasper, DL. Characterization of gonococcal antigens responsible for induction of bactericidal antibody in disseminated infection: the role of gonococcal endotoxins. J. Clin. Invest. 60: 1149-58, 1977.

9. Kasper, DL, and **Rice, PA**. Antigenic specificity of lipopolysaccharides to the bactericidal antibody response in gonococcal infection. *In* Immunobiology of *Neisseria gonorrhoeae*. Geo. F. Brooks, et al (eds.), American Society for Microbiology, Washington, DC, 1978, p. 187.

10. Posner, MR, Berk, S, and **Rice, PA**. Pneumococcal sepsis diagnosed by peripheral blood smear in multiple myeloma. Arch. Int. Med. 138: 1720-1721, 1978.

11. **Rice, PA**, and Loewenstein, MS. Epidemiology of Non-typhoid Salmonellosis: Present-Day Transmission Patterns, with special reference to Nosocomial Infections. Public Health Rev. 8: 155-176, 1979

12. **Rice, PA**. Bacterial Meningitis. *In* Current Therapy. Howard F. Conn (ed), W.B. Saunders Co., Philadelphia, PA, 1980, p. 41.

13. **Rice, PA**, Nugent, SF, and Kasper, DL. Antibodies that block killing of *Neisseria gonorrhoeae* aredirected against outer membrane proteins. Current Chemotherapy and Infectious Disease. John D. Nelson and Carlo Grassi (eds.), American Society for Microbiology, Washington, DC, 1980, p. 1237.

14. **Rice, PA**, and Baine, W. Prolonged intermittent diarrhea after Shiga dysentery; post-dysentery syndrome. South. Med. J. 73: 381-383, 1980.

15. **Rice, PA**, McCormack, WM, and Kasper, DL. Natural serum bactericidal activity against *Neisseria gonorrhoeae* isolates from disseminated, locally invasive and uncomplicated disease. J. Immunol. 124: 2105-2109, 1980.

16. **Rice, PA**, Huff, PM, Lamb, KJ, and O'Brien, JP. *Neisseria gonorrhoeae* surface antigens: their interaction with human sera. *In* Genetics and Immunobiology of Pathogenic Neisseria, Dan Danielson and Staffan Normack (eds.), Norrlands-tryck i Umea, AB, Umea, 1980, p. 255.

17. **Rice, PA**, and Goldenberg, DL. Clinical syndromes produced by *Neisseria gonorrhoeae* from disseminated infection are linked to serum sensitivity of infecting strains. *Ibid.* p. 283.

18. Berk, S, **Rice, PA**, Reynholds, CA, and Finland, M. Pneumococcal pericarditis: a persisting problem in contemporary diagnosis. Amer. J. Med. 70: 247-251, 1981.

19. **Rice, PA**. Bacterial meningitis. *In* Current Therapy, Howard F. Conn (ed.), W.B. Saunders Co., Philadelphia, PA, 1981, p. 41.

20. **Rice, PA**, and Goldenberg, DL. Clinical manifestations of disseminated infection caused by *Neisseria gonorrhoeae* are linked to differences in bactericidal reactivity of strains. Ann. Int. Med. 95: 175-178, 1981.

21. **Rice, PA**, and Kasper, DL. Characterization of serum resistance of *Neisseria gonorrhoeae* that disseminate: the roles of blocking antibody and gonococcal outer membrane proteins. J. Clin. Invest. 70:157-167, 1982.

22. Goldenberg, DL, Chisholm, PL, and **Rice, PA**. Experimental models of bacterial arthritis: A microbiologic and histopathologic characterization of the arthritis following the intra-articular injections of *Neisseria gonorrhoeae, Staphylococcus aureus,* group A streptococci, and *Escherechia coli.* J. Rheumatol. 10: 5-11, 1983.

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28. Goldenberg, DL, and **Rice, PA**. Disseminated gonococcal infection: current understanding of the clinical manifestations, laboratory features, and pathogenesis. *In* Progress in Clinical Rheumatology, Vol. I, A.S. Cohen (ed.), Grune and Stratton, New York, N.Y. 1984, p. 179.

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31. **Rice, PA**. Acute Bacterial meningitis. *In* Current Diagnosis 7, Rex B. Conn (ed.), W.B. Saunders Co., Philadelphia, PA., 1985, p. 909.

32. Karasic, RB, Trumpp, CE, Gnehm, HE, **Rice, PA** and Pelton, SI. Modification of otitis media in chinchillas rechallenged with nontypable *Haemophilus influenzae* and serologic response to outer membrane antigens. J. Infect. Dis 151:273-279, 1985.

33. Gnehm, HE, Pelton, SI, Gulati, S, and **Rice, PA**. Characterization of antigens from nontypable *Haemophilus influenzae* recognized by human bactericidal antibodies: The role of Haemophilus outer membrane proteins. J. Clin. Invest. 75:1645-1658, 1985.

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Pending:
U.S.: Serial No. 07/688, 714, filed 10/22/87

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ABSTRACTS

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EXHIBIT B

PEP1 (12 mer)

I	P	V	L	D	E	N	G	L	F	A	P
ATT	CCC	GTT	TTG	GAC	GAG	AAC	GGG	TTA	TTT	GCT	CCG

CA1(AB2) VL sequence

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1                   5                  10                  15
 E   L   M   M   T   Q   S   P   S   S   L   T   A   S   L
GAG CTC GTG ATG ACA CAG TCT CCA TCC TCC CTG ACT GCA TCT CTG
Sac I
                                    ←-------------CDR 1-------

16                  20                  24                  30
 G   G   K   V   T   I   T   C   K   A   S   Q   D   I   N
GGA GGC AAA GTC ACC ATC ACT TGC AAG GCA AGC CAA GAC ATT AAC

-------------→
31          34                  40                  45
 K   Y   I   A   W   Y   Q   H   K   P   G   K   G   P   R
AAG TAT ATA GCT TGG TAC CAA CAC AAG CCT GGA AAA GGT CCT AGG

                ←----------CDR 2----------→
46                  50                  56                  60
 L   L   I   H   Y   T   S   T   L   Q   P   G   I   P   S
CTG CTC ATA CAT TAC ACN TCT ACA TTA CAG CCA GGC ATC CCA TCA

61                  65                  70                  75
 R   F   S   G   S   G   S   G   R   D   Y   S   F   S   I
AGG TTC AGT GGA AGT GGG TCT GGG AGA GAT TAT TCC TTC AGC ATC

                                                    ←------
76                  80                  85                  89
 S   N   L   E   P   E   D   I   A   T   Y   Y   C   L   Q
AGC AAC CTG GAG CCT GAA GAT ATT GCA ACT TAT TAT TGT CTA CAG

-------CDR 3---------→
91                  96                 103
 Y   D   N   L   W   T   F   G   G   G   T   K   L   E   I
TAT GAT AAT CTG TGG ACG TTC GGT GGA GGC ACC AAG CTT GAA ATC
                                        Hind III
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CA1 (AB2) VH sequence

```
1          3              6                 10                          16
 Q    G    Q    L    L    E    S    G    G    G    L    V    Q    P    G    G
CAG  GTG  CAA  CTG  CTC  GAG  TCT  GGG  GGA  GGT  TTA  GTG  CAG  CCT  GGA  GGG
                   Xho I

                                                                  ←CDR1-
17             20             23             26                  30   31
 S    L    K    L    S    C    A    A    S    G    F    T    F    S    S    Y
TCC  CTG  AAA  CTC  TCC  TGT  GCA  GCC  TCT  GGA  TTC  ACT  TTC  AGT  AGC  TAT

----------→
          35                       40                  45              48
 T    M    S    W    V    R    Q    T    P    E    K    R    L    E    W    V
ACC  ATG  TCT  TGG  GTT  CGC  CAG  ACT  CCA  GAG  AAG  AGG  CTG  GAG  TGG  GTC

     ←-----------------------------------CDR2--------------------
49   50        52   52a           55                  60
 A    Y    I    S    N    G    G    G    S    T    Y    Y    P    D    T    V
GCA  TAC  ATT  AGT  AAT  GGT  GGT  GGT  AGC  ACC  TAC  TAT  CCA  GAC  ACT  GTA

------→
     65                  70                  75                  79
 K    G    R    F    T    I    S    R    D    N    A    K    N    T    L    Y
AAG  GGC  CGA  TTC  ACC  ATC  TCC  AGA  GAC  AAT  GCC  AAG  AAC  ACC  CTG  TAC

80        82   82a  82b  82c  83        85                  90        92
 L    Q    M    S    S    L    K    S    E    D    T    A    M    Y    Y    C
CTG  CAA  ATG  AGC  AGT  CTG  AAG  TCT  GAG  GAC  ACG  GCC  ATG  TAT  TAC  TGT

          ←-----------CDR3-----------→
93        95                            102                 108
 A    R    H    G    Y    Y    A    M    D    Y    W    G    Q    G    T    S
GCA  AGA  CAT  GGT  TAC  TAT  GCT  ATG  GAC  TAC  TGG  GGT  CAA  GGA  ACC  TCA

109            113            117
 V    T    V    S    S    A    N    S    K
GTC  ACC  GTC  TCC  TCA  GCG  AAT  TCT  AAG
                       EcoR I
```

BLAST 2 SEQUENCES

This tool produces the alignment of two given sequences using BLAST engine for local alignment.
The stand-alone executable for blasting two sequences (bl2seq) can be retrieved from NCBI ftp site
Reference: Tatiana A. Tatusova, Thomas L. Madden (1999), "Blast 2 sequences - a new tool for comparing protein and nucleotide sequences", FEMS Microbiol Lett. 174:247-250

Program [blastn] Matrix [Not Applicable]

Parameters used in BLASTN program only:
Reward for a match: [1] **Penalty for a mismatch:** [-2]

☐ Use Mega BLAST Strand option [Both strands]

Open gap [5] and extension gap [2] penalties
gap x_dropoff [50] expect [10.0] word size [11] Filter ☑ [Align]

Sequence 1 Enter accession or GI [PEP1] or download from file [ ]
or sequence in FASTA format from: [0] to: [0]

```
ATT CCC GTT TTG GAC GAG AAC GGG TTA TTT GCT CCG
```

Sequence 2 Enter accession or GI [CA1 VH] or download from file [ ]
or sequence in FASTA format from: [0] to: [0]

```
AGC TAT ACC ATG TCT TGG GTT CGC CAG ACT CCA GAG AAG AGG CTG
GAG TGG GTC GCA TAC ATT AGT AAT GGT GGT GGT AGC ACC TAC TAT
CCA GAC ACT GTA AAG GGC CGA TTC ACC ATC TCC AGA GAC AAT GCC
AAG AAC ACC CTG TAC CTG CAA ATG AGC AGT CTG AAG TCT GAG GAC
ACG GCC ATG TAT TAC TGT GCA AGA CAT GGT TAC TAT GCT ATG GAC
TAC TGG GGT CAA GGA ACC TCA GTC ACC GTC TCC TCA GCG AAT TCT
AAG
```

[Align] [Clear Input]

Comments and suggestions to *blast-help@ncbi.nlm.nih.gov*

Blast 2 Sequences results

BLAST 2 SEQUENCES RESULTS VERSION BLASTN 2.2.5 [Nov-16-2002]

Match: 1 Mismatch: -2 gap open: 5 gap extension: 2
x_dropoff: 50 expect: 10.0 wordsize: 11 Filter ☑ Align

Sequence 1 lcl|seq_1 **Length** 36

Sequence 2 lcl|seq_2 **Length** 363

No significant similarity was found

BLAST 2 SEQUENCES

This tool produces the alignment of two given sequences using BLAST engine for local alignment.
The stand-alone executable for blasting two sequences (bl2seq) can be retrieved from NCBI ftp site
Reference: Tatiana A. Tatusova, Thomas L. Madden (1999), "Blast 2 sequences - a new tool for comparing protein and nucleotide sequences", FEMS Microbiol Lett. 174:247-250

Program [blastn] Matrix [Not Applicable]

Parameters used in BLASTN program only:
Reward for a match: [1] **Penalty for a mismatch:** [-2]

☐ Use Mega BLAST Strand option [Both strands]

Open gap [5] and extension gap [2] penalties
gap x_dropoff [50] expect [10.0] word size [11] Filter ☑ [Align]

Sequence 1 Enter accession or GI [PEP1] or download from file [ ]
or sequence in FASTA format from: [0] to: [0]

```
ATT CCC GTT TTG GAC GAG AAC GGG TTA TTT GCT CCG
```

Sequence 2 Enter accession or GI [CA1 VL] or download from file [ ]
or sequence in FASTA format from: [0] to: [0]

```
GAG CTC GTG ATG ACA CAG TCT CCA TCC TCC CTG ACT GCA TCT CTG
GGA GGC AAA GTC ACC ATC ACT TGC AAG GCA AGC CAA GAC ATT AAC
AAG TAT ATA GCT TGG TAC CAA CAC AAG CCT GGA AAA GGT CCT AGG
CTG CTC ATA CAT TAC ACN TCT ACA TTA CAG CCA GGC ATC CCA TCA
AGG TTC AGT GGA AGT GGG TCT GGG AGA GAT TAT TCC TTC AGC ATC
AGC AAC CTG GAG CCT GAA GAT ATT GCA ACT TAT TAT TGT CTA CAG
TAT GAT AAT CTG TGG ACG TTC GGT GGA GGC ACC AAG CTT GAA ATC
```

[Align] [Clear Input]

Comments and suggestions to *blast-help@ncbi.nlm.nih.gov*

Blast 2 Sequences results

BLAST 2 SEQUENCES RESULTS VERSION BLASTN 2.2.5 [Nov-16-2002]

Match: 1 Mismatch: -2 gap open: 5 gap extension: 2
x_dropoff: 50 expect: 10.0 wordsize: 11 Filter ☑ Align

Sequence 1 lcl|seq_1 **Length** 36

Sequence 2 lcl|seq_2 **Length** 315

No significant similarity was found

PEPI-3 p16 sequence

XhoI

1 CCG ***CTC GAG*** AAA AGA GAG GCT GAA GCT GGT CCG ATT CCC GTT TTG 45
1 P L E K R E A E A G P I P V L 15
---------**Forward primer**----------I---------**PEPI**---------

BamHI

46 GAC GAG AAC GGG TTA TTT GCT CCG AGT CCG ***GGA TCC*** AGG AAC CGC 90
16 D E N G L F A P S P G S R N R 30
----------I **SpacerI**----------

91 TGG GAG GAG CCT GAC CAG CAG CTC TAC AAC GTA GAG GCC AGT GGA 135
31 W E E P D Q Q L Y N V E A S G 45
----**1st p16**----------I---

BanII

136 TCT GGT GGA GG***G GGC TC***T GGT GGA GGT GGA AGC GGA TCT CGG AAC 180
46 S G G G G S G G G G S G S R N 60
----------**Spacer**----------I-------

181 CGC TGG GAG GAG CCT GAC CAG CAG CTC TAC AAC GTA GAG GCC AGT 225
61 R W E E P D Q Q L Y N V E A S 75
----**2nd p16**----------I

BspEI

226 GGA TCT GGT GGA GGT GGT ***TCC GGA*** GGA GGT GGA AGT GGA TCT CGG 270
76 G S G G G G S G G G G S G S R 90
----------**Spacer**----------I---

271 AAC CGC TGG GAG GAG CCT GAC CAG CAG CTC TAC AAC GTA GAG GCA 315
91 N R W E E P D Q Q L Y N V E A 105
----**3rd p16**----------

SacII

316 AGT GGA TCT GAA GAG TTC TGA CTC AAG ***CCG CGG*** GGA 351
106 S G S E E F Stop
---I **SpacerI TripeptideI----Backward primer----**

Enzyme cleavage sites are italicized.